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To: Pediatric Vaccine Providers

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Date: March 24, 2013

Subject: Cervarix® Vaccine Added to MDPH Formulary

The Massachusetts Department of Public Health (MDPH) is pleased to announce the addition of Cervarix® vaccine, manufactured by GlaxoSmithKline (GSK), to its current formulary effective April 1, 2014. MDPH had previously been distributing only Gardasil® vaccine, manufactured by Merck, for all human papillomavirus (HPV) vaccine orders. This expansion is a result of a formal recommendation to the Department by the Massachusetts Vaccine Purchasing Advisory Council (MVPAC) after deliberations during their January 2014 meeting.

The addition of Cervarix® offers providers a choice for HPV vaccine formulations for females. **Please note that Cervarix® is NOT approved for use in males so providers who would like to use Cervarix® in their practice will need to continue to order Gardasil® for use in their male patients**.

Practices maintaining both HPV vaccine formulations in their practice must ensure they have appropriate systems in place to prevent medical errors resulting from inadvertent administration of Cervarix® to a male patient. Therefore, it is very important that you review the attached table which outlines the differences in composition, approved use and schedules of the Quadrivalent/HPV4 (Gardasil®) and Bivalent/HPV2 (Cervarix®) formulations of HPV vaccine.

Remember: state-supplied HPV vaccines are only available to VFC-eligible children 11 through 18 years of age. Providers will need to privately purchase HPV vaccine for those children who are privately insured.

Vaccine Ordering

If you currently order vaccines using the Vaccine Management Module in the MIIS and you want to add Cervarix® as an HPV formulation you would like to order, you will need to perform an additional step the first time you order the new formulation. Because the new formulation is not currently in your inventory, you will need to select "Add Vaccine from Formulary" at the bottom of the screen after you request doses of the other vaccines you are ordering. Then, select Cervarix®. Because this vaccine will appear in your inventory after you receive the vaccine shipment, you will not have to perform this additional step when you place your subsequent order.

If you still are not using the Vaccine Management Module of the MIIS because you are not registered we strongly encourage you to register with the MIIS at: https://contactmiis.info/enrollmentSite.asp and click "Begin Site Enrollment". If you have questions about registration, please call the MIIS Help Desk at 617-983-4335 or e-mail them at MIIShelpdesk@state.ma.us. If you are registered but have questions regarding placing your first online order, please call the Vaccine Unit at 617-983-6828.

The latest paper version of the MDPH *Vaccine Order Form* and *Vaccine Aggregate Report Form* are also attached to this memorandum and available on the MDPH website at www.mass.gov/dph/imm.

Please keep in mind that if you decide at a later date to stop using Cervarix®, ensure all existing inventories are used. Vaccine doses should never be allowed to expire before use or restitution (in the form of privately purchasing replacement doses) may be required.

Questions

For questions about **vaccine availability and ordering**, please call the Vaccine Management Unit at 617-983-6828.

For questions about **vaccine recommendations**, please call the Immunization Program at 617-983-6800 and ask to speak to an immunization epidemiologist or nurse.

(Attachment)

Massachusetts Department of Public Health
Immunization Program

Human Papillomavirus Vaccines
Composition, Approved Use and Schedules

Quadrivalent/HPV4 (Gardasil®)	Name	Bivalent/HPV2 (Cervarix®)
Merck	**Manufacturer**	GlaxoSmithKline
6, 11, 16, 18	**Types**	16, 18
Saccharomyces cerevisiae expressing L1	**Manufacturing**	*Trichoplusia ni* insect lines infected with L1 encoding recombinant baculovirus
AAHS: Amorphous aluminum hydroxyphosphate sulfate	**Adjuvant**	**ASO4:** 3-*O*-desacyl-4'monophosphoryl lipid A adsorbed onto aluminum hydroxide
Females: Anal, cervical, vaginal and vulvar precancer and cancer; genital warts **Males:** Anal precancer and cancer; genital warts	**Indications**	**Females:** Cervical precancer and cancer **Males:** Not approved for use in males
Severe allergic reaction to a previous dose or a vaccine component, including yeast.	**Contraindications Related to Vaccine Components**	Severe allergic reaction to a previous dose or a vaccine component. Note on latex: The tip caps of the prefilled syringes may contain natural rubber latex which may cause allergic reactions in latex-sensitive individuals.
3 dose series: 0, 2, 6 months[1]	**Schedule (IM)**	3 dose series: 0, 1, 6 months[1]

[1] ACIP recommends administering a 3-dose series of HPV vaccine on a schedule of 0, 1-2 and 6 months. Administer the second dose 1 to 2 months after the first dose and the third dose 6 months after the first dose (at least 24 weeks after the first dose).

Sources:

Gardasil Package Insert and Gardasil Patient Information (Source: FDA web site)

Cervarix Package Insert and Patient Information (Source: FDA website)

CDC. MMWR 2013;Supplement/62. Recommended US Immunization Schedules for Children and Adolescents, 2013.

CDC. Epidemiology and Prevention of Vaccine Preventable Diseases. HPV Chapter.

CDC. MMWR, 2011;60. Policy Note: Use of HPV4 in Males

CDC. MMWR 2010;59. FDA Licensure of Bivalent Human Papillomavirus Vaccine (HPV2, Cervarix) for Use in Females and Updated HPV Vaccination Recommendations from ACIP

CDC. MMWR 2010;59 Quadrivalent Human Papillomavirus Vaccine (HPV4, Gardasil) for Use in Males and Guidance from ACIP

CDC. MMWR 2007;56(RR-2). Quadrivalent Human Papillomavirus Vaccine – Recommendations from the ACIP